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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HUMPHREY, LOUISE WANG ZHIYING	
ART UNIT	**PAPER NUMBER**
1648	

MAIL DATE	DELIVERY MODE
10/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/523,038	SMITH ET AL.	
	Examiner	Art Unit	
	Louise Humphrey, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-124* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-124* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

Restriction is required under 35 U.S.C. §121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-24, 27, 36, 47-65 and 121-124, drawn to the special technical feature of a chimeric protein comprising a protein transduction domain and a deaminase domain; and a composition comprising the chimeric protein.

Group II, claim(s) 25, drawn to the special technical feature of a chimeric protein comprising a protein transducing domain, a deaminase domain comprising a CTD-1, and an anchor oligonucleotide.

Group III, claim(s) 26, drawn to the special technical feature of a CEM15 mimetic.

Group IV, claim(s) 28, drawn to the special technical feature of a method of interrupting HIV infectivity comprising contacting an HIV-infected cell or a cell prior to HIV infection with a chimeric protein comprising a protein transduction domain and a deaminase domain.

Group V, claim(s) 29-32, drawn to the special technical feature of a method of treating a subject with an HIV infection or at risk for an HIV infection comprising administering to the subject an effective amount of the chimeric protein comprising a protein transduction domain and a deaminase domain.

Group VI, claim(s) 33-35 and 66-77, drawn to the special technical feature of an isolated nucleotide sequence that encodes the chimeric protein comprising a protein transduction domain and a deaminase domain; a vector comprising the nucleotide sequence; and a recombinant host cell comprising the vector.

Group VII, claim(s) 37-46, drawn to the special technical feature of a method of screening for a deaminase mimetic.

Group VIII, claim(s) 78, drawn to the special technical feature of an isolated B lymphblastic cell or other receptive cell which has taken up the chimeric protein comprising a protein transduction domain and a deaminase domain.

Group IX, claim(s) 79-97, drawn to the special technical feature of a method of inducing production of immunoglobulins in a B lymphocyte cell.

Group X, claim(s) 98-110 and 118-120, drawn to the special technical feature of a method of inducing an immune response in a subject comprising administering the chimeric protein comprising a protein transduction domain and a deaminase domain.

Group XI, claim(s) 111-117, drawn to the special technical feature of a method of treating a subject comprising administering a population of B lymphocyte cells that have taken up the chimeric protein comprising a protein transduction domain and a deaminase domain.

The inventions listed as Groups I-XI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

As set forth above, each Group requires a technical feature that is not required by any of the other groups.

According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding special technical feature is a contribution over the prior art. The technical feature of Group I is chimeric protein comprising a protein transduction domain and a deaminase domain, which is shown by Yang *et al.* (1997, IDS No. A389 filed 12/08/05) and Schwarze *et al.* (1999, IDS No. A304 filed on 12/08/05) to lack an inventive step.
Yang *et al.* disclose a chimeric protein of APOBEC-1 fused to CMPK, APOBEC-1-CMPK, from N-to C-terminus (page 13075, Materials and Methods, Plasmids) and that CMPK functions as a cytoplasmic localization protein. See page 13077, right column.
Yang et al. do not disclose the protein transduction domain.
Schwarze *et al.* describe fusion proteins containing an NH_2-terminal 11- amino acid protein transduction domain (PTD) from the HIV Tat protein (the sentence bridging p. 1569 and 1570). Schwarze *et al.* report protein transduction of over 50 proteins ranging in size from 15 to 120 kD into a wide variety of human and murine cell types *in vitro* (p. 1570, top ¶) and delivery of biologically active fusion protein to all tissues in mice, including the brain (abstract).
Since the claimed invention is known in the art, it does not make a contribution over the prior art, therefore unity is lacking.

Species Election

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of genus A to C are as follows:

A. genus of deaminase:
    i. CEM15 (claims 5-8, 21);
    ii. CEM15 mimetic (claim 27);
    iii. activation-induced deaminase (AID) (claims 47, 51, 52);
B. genus of protein transducing domain:
    1. HIV Tat protein (claims 2-4 or 48-50);
    2. poly-arginine peptide (claim 2 or 48);
    3. poly-lysine peptide (claim 2 or 48);
    4. third alpha helix of antennapedia homeodomain protein (claim 2 or 48);
    5. HSV-1 virion protein (VP) 22 (claim 2 or 48);
    6. HIV-1 Vpr protein (claim 2 or 48);
C. genus of the third peptide of which the chimeric protein is comprised:
    a. hemagglutinin epitope tag (claims 9-10 or 58-59);
    b. polyhistidine tag (claim 11 or 60);
    c. protein cleavage site (claim 15); and
    d. solubility enhancer (claims 12-14 or 53-57).

Except when Applicant elects Group III or VII, Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 1, 16-20, 22-25, 28-36, 47 and 63-124.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the same reasons as the Groups.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Restriction to Single Sequence Election

Note that this is not a species election and is separate from a group election.

For the deaminase domain in the chimeric protein, claims 1-124 specifically claim multiple amino acid sequences, SEQ ID NO:43 and SEQ ID NO:3, encoding different proteins, which are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and

distinct inventions within the meaning of 35 U.S.C. §121. Each such amino acid sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. §121 and 37 CFR 1.141 *et seq* (See MPEP §803.04). Each sequence is not considered to be a proper member of a Markush group. See M.P.E.P. § 803.02. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility. As such, sequences in each of claims 6-9 and 11 are not considered to constitute a proper genus/Markush, and are therefore subject to additional restriction.

Furthermore, a search of more than one (1) of the sequences present in these claims presents an undue burden on the Patent and Trademark Office due to the complex nature of the search in terms of computer time needed to perform the search and the subsequent analysis of the search results by the examiner. Each of the SEQ ID NO's is a unique and separately patentable sequence, requiring a non-coextensive search for the prior art.

In view of the foregoing, one (1) sequence is considered to be a reasonable number of sequences for examination. Accordingly, applicants must further elect ONE single epitope sequence, identified by a SEQ ID NO., which if determined to be patentable, would also be patentably distinct from other sequences. Failure to elect a specific sequence will be considered to be non-responsive reply.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species and/or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention and/or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Advisory Information

Applicant is advised that the final rules on claims and continuations were published in the Federal Register Tuesday, August 21, 2007. As of November 1, 2007, the claims in each application may not exceed 5 independent claims or 25 total claims absent the applicant assisting the examination process through the filing of an Examination Support Document (ESD). The following is taken from the published rules package:

- **Applicants may present, without an ESD, up to:**
    - **Five (5) independent claims or**
    - **Twenty-five (25) total claims in an application.**
- **Applicant may present more than 5/25 claims, if applicant files an ESD before the first Office action on the merits (FAOM).**
- **The 5/25 claim threshold does not count withdrawn claims.**
    - **Applicant may provide a suggested restriction requirement (SRR) before first Office action or a restriction requirement.**
- **The 5/25 claim threshold does count all of the claims present in other copending application(s) having a patentably indistinct claim, but not the claims in issued patents.**
    - **Applicant may present up to 15/75 claims via an initial application and 2 continuation or CIP applications prosecuted serially.**

The final rules will become effective November 1, 2007, and will apply to all pending applications as of that date. Applicants are advised to ensure that the elected claims are compliant with the new rules to avoid delay of prosecution. There will be no change to the examiner practice prior to the date the rules become effective. Information on the new rules will be available at:

http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/clmcontfinalrule.html

If Applicant has any questions concerning the new rules, email patentpractice@uspto.gov or call 571-272-7704.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey, Ph.D. whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Thu, 9:00 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Assistant Patent Examiner
17 September 2007

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